Remarks:

Claims 3-4, 8-12, 15-19, 21-25 and 31 remain for consideration in this application with claims 12, 19, and 31 being in independent format. As an initial matter, Applicant wishes to point out that claim 31 is still pending the present application. However, the Examiner does not appear to have considered claim 31 in the Office Action. Applicant assumes this was merely an oversight and accordingly, includes claim 31 in the following response.

In the Office Action, the Examiner has withdrawn the previous prior art rejections; however, the Examiner has rejected claims 3-4, 8-12, 15-19, and 21-25 as failing to comply with the enablement and written description requirements of 35 U.S.C. § 112, first paragraph.

With regard to enablement, the Examiner asserts that "the specification provides no support for any method with 80% accuracy, more specifically for chronic HCV infection" and "no guidance in predicting how the method can be made/used in distinguishing between a chronic HCV infection and an active acute HCV infection." Accordingly, the Examiner alleges it would require undue experimentation to practice the claimed method.

To begin, Applicant believes that the Examiner has misunderstood the presently claimed subject matter. The present application is not concerned with distinguishing between acute and chronic HCV infection, because in terms of the HCV infection itself, the difference between acute and chronic HCV is merely a matter of time. That is, an acute infection occurs soon after being exposed to the virus. If the immune system is unable to clear the infection (usually after six months), then the disease is labeled as being "chronic." Thus, in both "phases" the virus persists. Moreover, they are not really separate phases rather, chronic HCV is simply defined as when a person tests

positive for the HCV virus 6 months after exposure. Meaning that chronic HCV infection is really just an acute infection that has not cleared. Applicant has attached an article entitled "Differences between Acute and Chronic HCV," for the Examiner's reference.

The Examiner argues that invention is not enabled because "for both types of infections, the samples would test positive for HCV antibodies and have a higher OD reading compared to a sample in which the individual has recovered from the infection." Office Action 4/6/2007, Page 4. Applicant agrees with the Examiner that chronic and acute HCV would have higher OD readings than an infection that has cleared, and believes this statement fully supports Applicant's position that the present application is fully enabled. That is, Applicant has continuously argued that the problem associated with determining HCV-positive or -negative results (i.e., initial testing for HCV antibodies) is separate and distinct from the problem of determining whether a *known* HCV-positive sample is chronically infected. Specifically, the presently claimed methods are limited to predicting chronic infection in samples that have already tested positive for HCV antibodies (i.e., a confirmation test to determine whether the infection has cleared or whether the infection is chronic). Confirmation tests are generally given several months after the anti-HCV positive test, at which time the concern is distinguishing between a chronic HCV infection and a cleared HCV infection, and not determining acute versus chronic. That is, the labels "acute" and "chronic" are basically synonymous at this point of the HCV disease. Because Applicant is not concerned with distinguishing between acute and chronic HCV infections, the Examiner's rejections that the Applicant has not enabled a method of distinguishing between chronic and acute is moot. Applicant maintains that the presently claimed method of qualitatively predicting whether or not a known

HCV-positive sample is chronically infected has been enabled and fully meets the written description requirements. Moreover, Applicant believes this fact has been acknowledged by the Examiner in the rejection.

In particular, in the Office Action, the Examiner stated that the "specification discloses a method that qualitatively determines whether the virus is present or not (that is, by determining the OD readings of the antibodies in the sample following antibody assays)." Office Action 4/6/2007, Page 4. The Examiner also acknowledges that the "specification provides data that compare the optical density measurements for HCV antibody and HCV RNA test to suggest a correlation between the two measurements for predictability (page 13). Table 3 (page 15) shows the OD readings of samples against their PCR HCV RNA levels, including undetectable and detectable levels." Office Action 4/6/2007, Page 3. Further, the Examiner notes that the specification does "describe a method in qualitatively predicting whether one has an HCV infection or not." Office Action 4/6/2007, Pages 3-4. And the Examiner has stated that the presently claimed method is capable of distinguishing between chronic and cleared infections based on OD readings. Office Action 4/6/2007, Page 4. Accordingly, it appears the Applicant and Examiner are in agreement that the presently claimed method of predicting whether or not an individual testing positive for anti-HCV is chronically infected based upon the results from an antibody-based assay and a measurement of the OD of the solution which contains the sample and the antibodies to HCV is fully described and enabled in the specification.

Regarding the written description rejection, the Examiner asserted that "the specification does not describe how the OD readings of such antibodies can specifically predict chronic HCV with

80% accuracy or even distinguish from those who have acute HCV." Office Action 4/6/2007, Page 5. Applicant believes that the foregoing remarks regarding enablement adequately address this rejection as well. Again, distinguishing between acute and chronic infection is not the aim of the present method. That is, in the art, the point of distinction is between a cleared HCV infection (i.e., no virus present) and chronic infection (virus still present), not between acute and chronic because the two "phases" of the disease, acute and chronic, are essentially the same in that "chronic HCV" is merely the continuation of the acute infection, and acute infection that persists long term.

Moreover, Applicant submits that the presently claimed method, is described in the specification in such a way as to reasonably convey to one skilled in the art that Applicant was in possession of the claimed invention at the time of filing. In particular, Example 1 gives detailed procedures and materials for performing the assays and taking OD measurement. In the disclosed method, the samples undergoing testing are contacted with a multiple-antigen system in a first assay which are reactive with different antibodies which may be in the samples. Thereafter, in preferred practice, a second assay is performed making use of three additional antigens. The latter are a part of the ORTHO HCZ version 3.0 ELISA Test System. Tables 1-3 provide the results and the correlation of the OD readings to whether or not HCV RNA serum was detected. The discussion analyzes the results in terms of predicting whether there is a chronic infection (i.e., whether the virus is still present). The specification gives specific examples of various OD measurements and the correlated accuracy of predicting chronic infection for various measurements. Moreover, the specification provides standard optical density values correlated with probabilities of chronic HCV infection, which can be used to predict whether an individual has chronic HCV infection and

discloses specific ranges of OD values that provide at least 80% accuracy. "The test results indicate that such accuracy is possible because of the 94 samples testing positive in the antibody-based assay and having an OD greater than 2.5, 89 tested positive for HCV RNA. Identical ranges apply for samples testing positive in the HCV antibody-based assay and having an OD of at least 2.36 as 94 of 99 samples subsequently tested positive for HCV RNA." Application page 16, lines 12-16. Moreover, "[o]f the 42 samples testing positive for HCV antibody which had an OD measurement of greater than 3.0, 41 subsequently tested positive for HCV RNA." Page 16, lines 1-2. Thus, contrary to the Examiner's assertions, the application describes specific antibody assays and OD measurements that would allow one skilled in the art to distinguish, with 80% accuracy, whether or not a sample known to be positive for anti-HCV is chronically infected (i.e., whether the virus is still present).

In view of the foregoing, a Notice of Allowance appears to be in order and such is courteously solicited. If any questions should remain, the Examiner is encouraged to contact the undersigned at 1-800-445-3460.

Any additional fee which is due in connection with this amendment should be applied against our Deposit Account No. 19-0522.

Respectfully submitted,

Date: October 2, 2007

By _____

John M. Collins, Reg. No. 26,262
2405 Grand Boulevard, Suite 400
Kansas City, Missouri 64108
816/474-9050

ATTORNEYS FOR APPLICANT